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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
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| 09/314,161 | 05/19/99 | EISENBACH-SCHWARTZ M | EIS-SCHWARTZ |

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| EXAMINER | |
|---|---|
| BUNNER, B | |
| ART UNIT | PAPER NUMBER |
| 1647 | 9 |

DATE MAILED: 02/28/01

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/314,161 | EISENBACH-SCHWARTZ ET AL. | |
| | Examiner | Art Unit | |
| | Bridget E. Bunner | 1647 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *02 November 2000* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-37* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claims *1-37* are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. § 119**

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

**Attachment(s)**

15) ☐ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
18) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other: .

## DETAILED ACTION

### *Election/Restrictions*

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-8, 16, and 19, drawn to a method for preventing or inhibiting neuronal degeneration in the central nervous system or peripheral nervous system comprising administering to an individual NS-specific activated T cells, classified in class 424, subclass 93.1.

II. Claims 1-3 and 9-16, drawn to a method for preventing or inhibiting neuronal degeneration in the central nervous system or peripheral nervous system comprising administering to an individual a NS-specific antigen or a peptide derived from a NS-specific antigen, classified in class 514, subclass 2.

III. Claims 1-3 and 16, drawn to a method for preventing or inhibiting neuronal degeneration in the central nervous system or peripheral nervous system comprising administering to an individual a nucleotide sequence encoding a NS-specific antigen or a nucleotide sequence encoding a peptide derived from a NS-specific antigen, classified in class 514, subclass 44.

IV. Claim 17, drawn to a method for preventing or inhibiting neuronal degeneration in the central nervous system or peripheral nervous system comprising administering a composition for up-regulating B7.2 costimulatory molecule in class 514, subclass not determinable.

V. Claim 18 and 37, drawn to a cell bank comprising T cells which have been expanded against central nervous system antigen, classified in class 435, subclass 325.

VI. Claims 20-27 and 35-36, drawn to a composition for preventing or inhibiting neuronal degeneration in the central nervous system or peripheral nervous system comprising NS-specific activated T cells, classified in class 435, subclass 325.

VII. Claims 20-22, and 28-36, drawn to a composition for preventing or inhibiting neuronal degeneration in the central nervous system or peripheral nervous system comprising a NS-specific antigen or a peptide derived from a NS-specific antigen, classified in class 530, subclass 300.

VIII. Claims 20-22, and 35-36, drawn to a composition for preventing or inhibiting neuronal degeneration in the central nervous system or peripheral nervous system comprising a nucleotide sequence encoding a NS-specific antigen or a nucleotide

sequence encoding a peptide derived from a NS-specific antigen, classified in class 536, subclass 23.1.

2. The inventions are distinct, each from the other because of the following reasons:

a. Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive groups that are directed to different products, restriction is deemed to be proper because these products constitute patentably distinct inventions for the following reasons. Groups V-VIII are directed to products that are distinct both physically and functionally, are not required one for the other, and are therefore patentably distinct. For example, the T cells of Invention V can be used than to deposit in a cell bank, such as in proliferation assays, immunotherapy, or polypeptide production. Invention VI encompasses activated T cells, which are cells that regulate and coordinate cell killing and antibody production. These cells recognize specific antigens displayed on the surface of cells. The DNA of Group VIII can be used other than to make the antigen/peptide of Group VII , such as a probe in nucleic acid hybridization assays. The protein(s) of Invention VII is unique from the nucleotide sequence (DNA) of Invention VIII. DNA is made of a different composition than proteins (nucleic acids vs. amino acids).

b. Similarly, although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive groups that are directed to different methods, restriction is deemed to be proper because these methods constitute patentably distinct inventions for the following reasons. Inventions I-IV are different methods because they require different ingredients, process steps, and endpoints. Groups I-IV are different methods requiring different method steps, wherein each is not required, one for another. For example, Invention I requires search and consideration of efficacy of therapy of administration of NS-specific activated T cells, which is not required by the other inventions. Invention II requires search and consideration of efficacy of therapy of NS-specific antigen

administration, which is not required by the other inventions. Invention III requires search and consideration of efficacy of therapy of administration of a nucleotide sequence encoding a NS-specific antigen, which is not required by the other inventions. Invention IV requires search and consideration of efficacy of therapy of administration of a composition that up-regulates or genetically manipulates B7.2 costimulatory molecule, which is not required by the other inventions.

c. Inventions VI and I are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product claimed can be used in materially different processes, such as diagnostic assays or polypeptide/polynucleotide purification.

d. Inventions VII and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product claimed can be used in materially different processes, such as in the production of antibodies or a probe in immunoassays.

e. Inventions VIII and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case,

the product claimed can be used in materially different processes, such as diagnostic, detection or immunopurification assays.

f. Inventions IV and V-VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions of Groups VI and VII-XII are unrelated products and method, wherein each is not required, one for another. For example, the claimed method of Invention IV does not recite the use or production of the T cells, antigen, peptide, and DNA of Inventions V-VIII.

3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, different search, and different classification, restriction for examination purposes as indicated is proper.

4. This application contains claims directed to the following patentably distinct species of the claimed invention:

A method for preventing or inhibiting neuronal degeneration in the central nervous system or peripheral nervous system for ameliorating the effects of injury or disease wherein the injury is:

Ia. spinal cord injury

Ib. blunt trauma

Ic. penetrating trauma

Id. hemorrhaging stroke

Ie. ischemic stroke

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 3-20 and 22-37 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

5. This application contains claims directed to the following patentably distinct species of the claimed invention:

A method for preventing or inhibiting neuronal degeneration in the central nervous system or peripheral nervous system for ameliorating the effects of injury or disease wherein the disease is:

If. diabetic neuropathy

Ig. senile dementia

Ih. Alzheimer's disease

Ij. Parkinson's disease

Ik. facial nerve palsy

Im. glaucoma

In. Huntington's chorea

Io. amyotrophic lateral sclerosis

Ip. non-arteritic optic neuropathy

Iq. vitamin deficiency

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 2, 4-21, and 23-37 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

6. This application contains claims directed to the following patentably distinct species of the claimed invention:

A method for preventing or inhibiting neuronal degeneration in the central nervous system or peripheral nervous comprising administering NS-specific activated T cells, wherein the activated T cells are:

Ir. autologous T cells

Is. allogenic T cells from related donors

It. HLA-matched or partially matched semi- or fully allogenic donors

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 2-3, 9-15, 17, 21-22, and 28-34 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

7. This application contains claims directed to the following patentably distinct species of the claimed invention:

A method for preventing or inhibiting neuronal degeneration in the central nervous system or peripheral nervous system comprising administering a NS-specific antigen wherein the antigen is:

Iu. myelin basic protein

Iv. myelin oligodendrocyte glycoprotein

Iw. proteolipid protein

Ix. myelin-associated glycoprotein

Iy. S-100

Iz. β-amyloid

IIa. Thy-1

IIb. P0

IIc. P2

IId. neurotransmitter receptors

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 2-4, 7-8, 17, 21-23, and 26-27 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

8. This application contains claims directed to the following patentably distinct species of the claimed invention:

A method for preventing or inhibiting neuronal degeneration in the central nervous system or peripheral nervous system comprising administering a peptide derived from a NS-specific antigen wherein the peptide corresponds to a sequence of myelin basic protein:

IIe. p11-30

IIf. p51-70

IIg. p91-110

IIh. p131-150

IIi. p151-170

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 2-4, 7-8, 17, 21-23, and 26-27 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

**If applicant selects Inventions I-VIII, one species from the nervous system injury group must be chosen to be fully responsive.**

**If applicant selects Inventions I-VIII, one species from the nervous system disease group must be chosen to be fully responsive.**

**If applicant selects Inventions I, V, or VI, one species from the NS-specific activated T cell group must be chosen to be fully responsive.**

**If applicant selects Inventions II, V, or VII, one species from the NS-specific antigen group must be chosen to be fully responsive.**

**If applicant selects Inventions II, V, or VII, one species from the peptide-derived group must be chosen to be fully responsive.**

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bridget E. Bunner whose telephone number is (703) 305-7148. The examiner can normally be reached on 7:30-4:00 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on (703) 308-4623. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Bridget E. Bunner
Art Unit 1647
February 26, 2001

GARY L. KUNZ
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600